Medtronic

MAY 25 2012

510(k) Summary

K120612

Date Prepared:	May 24, 2012
Submitter:	Medtronic Perfusion Systems 7611 Northland Drive Minneapolis, MN 55428 Establishment Registration Number: 2184009
Contact Person:	Kelley Breheim Associate Regulatory Affairs Specialist Phone: (763) 514-9831 Fax: (763) 367-8360 Email: Kelley.c.breheim@medtronic.com

Device Name and Classification

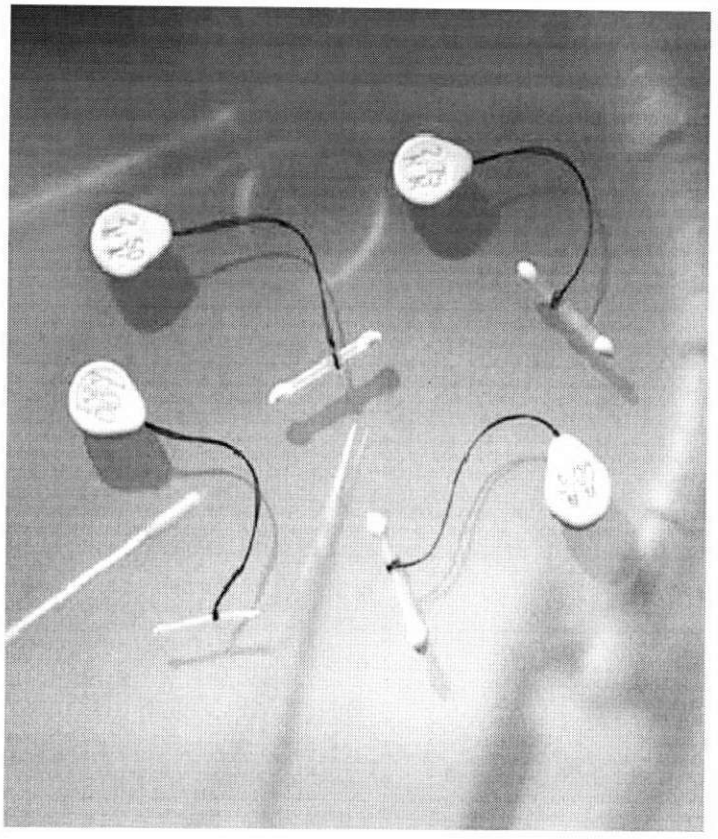
Trade Name:	Clearview® Intracoronary Shunts
Common Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulation Number:	21 CFR 870.4210
Product Code:	DWF
Classification:	Class II

Predicate Devices

Medtronic Clearview® Intravascular Arteriotomy Shunt (K993677)

Device Description

Clearview® Intracoronary Shunts consist of a flexible tube. Both ends of the tube feature a teardrop shaped tip made from radiopaque material. Tip diameters range from 1.00 mm to 3.00 mm. A tether with a tag made of radiopaque material is permanently attached to the shunts. The sizes of the shunts are indicated on the tag. These shunts are sterile, nonpyrogenic, disposable and single use only.



Indications for Use

These shunts are intended for use to shunt blood by the arteriotomy anastomosis site while the surgeon is making the anastomosis.

Comparison to Predicate Devices

A comparison of the modified product and the currently marketed Clearview® Intracoronary Shunts indicates the following similarities to the device which received 510(k) clearance:

- The technological characteristics have not changed from the predicate device. The same radiopaque material is used (organic barium sulfate to synthetic barium sulfate).
- No change to the operating principle was made.
- No design features have changed.
- Shelf life has not been impacted by the change.

Performance Testing Summary

Bench testing (non-clinical) was used to demonstrate that there was no discernible difference when changed from organic barium sulfate to synthetic barium sulfate.

Testing included:

- X-ray of the radiopaque material
- Biocompatibility testing of the material
- Suture pull test of the material

Clinical testing was not required to establish substantial equivalence.

Conclusion

Medtronic has demonstrated that the Clearview® Intracoronary Shunts are substantially equivalent to the predicate device based upon design and test results. Any noted differences do not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 25 2012

Medtronic, Inc.
c/o Ms. Kelley Breheim
8200 Coral Sea St. NE
Mounds View, MN 55119

Re: K120612
Trade/Device Name: Clearview Intracoronary Shunt
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: April 27, 2012
Received: April 30, 2012

Dear Ms. Breheim,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

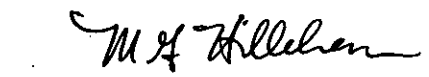
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120612

Device Name: Clearview® Intracoronary Shunts

Indications For Use:

These shunts (Clearview® Intracoronary Shunts) are intended for use to shunt blood by the arteriotomy anastomosis site while the surgeon is making the anastomosis.

Prescription Use _X___ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120612